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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,279	03/03/2004	Theodor Stern	26041	8931
20529 7590 06/29/2007 NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER VAKILI, ZOHREH	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 06/29/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/791,279	<b>Applicant(s)</b> STERN ET AL.	
	<b>Examiner</b> Zohreh Vakili	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____.  |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/17/2005, 8/11/2005, 10/31/2006.

**DETAILED ACTION**

**Claims 1-16 are presented for examination.**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kluger et al. (US PUB. No. 2002/0045873 A1) and in view of Zhao et al. (US Patent No. 6730057 B2).

Kluger et al. teach of a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, comprising (a) 3-80% by weight of a solid organic acid polymer; (b) 92-15% by weight of a solid organic acid, and (c) 5-30% of a wetting agent. Also disclosed is a delivery system for releasing an active agent comprising: (a) a deposition comprising the active agent; and (b) a polymeric support on which the deposition is deposited. The delivery system is especially useful in a catamenial tampon for insertion in a human vagina which comprises (a) an inner core comprising an absorbent material; (b) an outer layer comprising a liquid permeable material; and (c) the delivery system (see abstract).

Examples of solid organic acids are citric, inalic, maleic, fumaric, succinic, tartaric and oxalic acids. A preferred organic acid is citric acid. The organic acid comprises 92-15% of the formulation, and preferably 30-15% (see page 2, paragraph 002).

Examples of wetting agents which may be used in the formulation of the invention include glycerol, polyethylene glycol (PEG), polypropylene glycol (PPG) and surfactants with an HLB ranging from 10 to 18. Preferred wetting agents are glycerol and PEG-8000. The wetting agent comprises 5-30% of the formulation, and preferably 5-10% (see page 2, paragraph 0023).

Zhao et al. The flushable tampon applicators of the present invention comprise a total of from about 1% to about 99%, preferably from about 9% to about 59%, more preferably from about 15% to about 50% of biodegradable thermoplastic polymers by weight of the applicator. The biodegradable thermoplastic polymers can be used individually or as a combination of polymers provided that the biodegradable

thermoplastic polymers are degradable by biological and environmental means, and that they are compatible for combination with one or more water-dispersible polymers described hereinabove (see col. 9, lines 25-35). Nonlimiting examples of biodegradable thermoplastic polymers suitable for use in the flushable tampon applicators (see col. 9, lines 48-50). lactide polymers including lactide homopolymers and lactide copolymers; glycolide polymers including glycolide homopolymers and glycolide copolymers; and mixtures thereof. Preferred are aliphatic polyesteramides, diacids/diols aliphatic polyesters, aliphatic/aromatic copolyesters, lactic acid polymers, and lactide polymers (see col. 10, lines 1-10). Preferred aliphatic polyesteramides which are copolymers of aliphatic esters and aliphatic amides can be characterized in that these copolymers generally contain from about 30% to about 70% (see col. 10, lines 24-27). The flushable tampon applicators of the present invention can optionally comprise viscosity modifiers to increase the viscosity of the water-dispersible and biodegradable thermoplastic polymers described herein so that they can be molded using a preferred injection molding or any other molding technique described herein. Such viscosity modifiers are typically included at concentrations ranging from about 0.1% to about 5%, preferably from about 0.1% to about 2% by weight of the applicator. Nonlimiting examples of suitable viscosity modifiers include trifunctional alcohols such as trimethylolpropane, tetrafunctional alcohols such as pentaerythritol, trifunctional carboxylic acids such as **citric acid**, and the like (see col. 23, lines 28-40).

It is obvious to one of ordinary skill in the art to use a combination of the teachings of Kluger et al. along with the teachings of Zhao et al. to arrive at the

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formulation of the tampon. Kluger et al. discloses of a formulation for reducing the pH in a menstruating vagina by inserting a tampon made from solid organic acid polymer and solid organic acid and a wetting agent. Zhao et al. teach a flushable tampon applicators made from biodegradable components such as lactide copolymers and glycolide polymers.

One ordinary skilled in the art would have been motivated to use the teachings from Zhao et al. using the biodegradable components and incorporate it into the formulation taught by Kluger et al. and arrive at the claimed invention, a tampon made of biodegradable polymers for reducing the pH of a menstruating vagina. One would have been motivated to use these two teachings to make and use the tampon.

Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and as a whole, prima facie obvious.

### **Conclusion**

No claims of the present application are allowed.

Any inquiry concerning this communication should be directed to Zohreh Vakili, telephone number 571-272-3099. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m., Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.ushpo.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili  
Patent Examiner  
Art Unit 1614

ZV

June 15, 2007

*Ardin H. Marschel 6/25/07*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**